K111292

510(k) Summary: Luminos Agile

JUN - 3 2011

Company: Siemens Medical Systems, Inc.
1 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: May 4, 2011

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **General Information:**

Importer / Distributor:
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Establishment Registration Number:
2240869

Manufacturing Site:
SIEMENS AG Sector Healthcare
Siemensstr. 1
91301 Forchheim

2. **Contact Person:**
Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway G-01
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

3. **Device Name and Classification:**

Trade Name:	Luminos Agile
Classification Name:	Solid state x-ray imager (flat panel/digital imager)
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1650
Device Class:	Class II
Device Code:	90 MQB

4. **Device Description:**
Luminos Agile is a floor-mounted universal fluoroscopic x-ray diagnostic system (R/F system), that was developed for tableside examinations in combination with an Explorator. The modification is to replace the Image Intensifier / TV Camera with a solid state detector (flat panel/digital imager). The Explorator houses the flat panel solid state detector.

This modified AXIOM SIRESKOP SD will be marketed under the trade name Luminos Agile. The modification does not affect the intended use of the device nor does it alter its fundamental scientific technology.

Luminos Agile may be configured as a single tube system, with an under table tube or a dual tube system which features an additional 3D overhead tube crane, that can be moved longitudinally and laterally as well as vertically. The dual x-ray tube configuration provides a quick change between under table and over table exposure modes. The under table tube is used for fluoroscopy and radiographic exposures taken with the Digital Imaging System. The over table tube is suspended from an overhead tube support for exposures with a table Bucky or Bucky wall stand, either with film cassettes or solid state detector. The digital images produced by the solid state detector are recorded and displayed by the Fluorospot COMPACT digital imaging system. The table design remains unchanged while the new imaging chain is based on the AXIOM Luminos dRF described in premarket notification K062623 which received FDA Clearance on August 22. 2007.

5. **Intended Use:**
The Luminos Agile is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using either film cassettes or a digital mobile flat detector, it can perform a range of applications including general R/F, angiography and pediatric examinations.

Luminos Agile is applicable for emergency treatment on an outpatient basis, as well as for bedside examinations.

6. **Substantial Equivalence:**
The Luminos Agile with flat panel solid state detector is substantially equivalent to the commercially available Siemens systems, the AXIOM Luminos TF (AXIOM Sireskop SD) and the AXIOM Luminos dRF. The AXIOM Sireskop SD was described in premarket notification K051602 which received FDA Clearance on 07/07/2005. The AXIOM Sireskop SD was renamed later to AXIOM Luminos TF for marketing reasons. The change was documented in an NFJ. The AXIOM Luminos dRF was described in premarket notification K062623 which received FDA Clearance on August 22. 2007.

X-ray generation and control used with the Luminos Agile is identical to the AXIOM Luminos dRF. The Flat Detector Pixium 5100 and the Fluorospot Compact digital imaging system equipped with Luminos Agile are identical to the detector and imager used in the AXIOM Luminos dRF.

7. **Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device:**
Luminos Agile is not a stand-alone device, but functions as the platform for specific X-ray components (X-ray generator, X-ray tube and housing, Exploratory with flat panel solid state detector, mobile flat detector, digital imaging system, Bucky cassette holder, Bucky detector holder and Bucky wall stand etc.).

Luminos Agile is a modified AXIOM Sireskop SD. The principal device Luminos Agile features a solid state detector instead of an x-ray image intensifier like the predicate AXIOM Sireskop SD. The design of the Luminos Agile's imaging chain is based on the design of the second predicate the AXIOM Luminos dRF. Also, the Luminos Agile shares the same x-ray- and software components with the AXIOM Luminos dRF. (Table base, Generator, X-ray tube and housing, beam-limiting-devise flat detector, digital image processing device, etc.).

Many of these components used in Luminos Agile are either commercially available with current Siemens systems or include minor modifications to existing components.

8. **General Safety and Effectiveness Concerns:**
Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the Luminos Agile is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed. Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

9. **Conclusion as to Substantial Equivalence:**
The Luminos Agile is intended for the same indications for use as the predicate AXIOM Sireskop SD. The imaging chain has been modified to include a flat panel detector. The portfolio of accessories is the same as with the predicate AXIOM Sireskop SD to compliment the needs of the Fluoroskopy suite. It is Siemens opinion, that the Luminos Agile is substantially equivalent to the AXIOM Sireskop SD.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Patricia D. Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway, E-50
MALVERN PA 19355

AUG 20 2013

Re: K111292
Trade/Device Name: Luminos Agile
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA and IZI
Dated: May 4, 2011
Received: May 6, 2011

Dear Ms. Jones:

This letter corrects our substantially equivalent letter of June 3, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K111292

Device Name: Luminos Agile

Indications for Use:

The Luminos Agile is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using either film cassettes or a digital mobile flat detector, it can perform a range of applications including general R/F, angiography and pediatric examinations.

Luminos Agile may be used for emergency treatment on an outpatient basis, as well as for bedside examinations.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111292